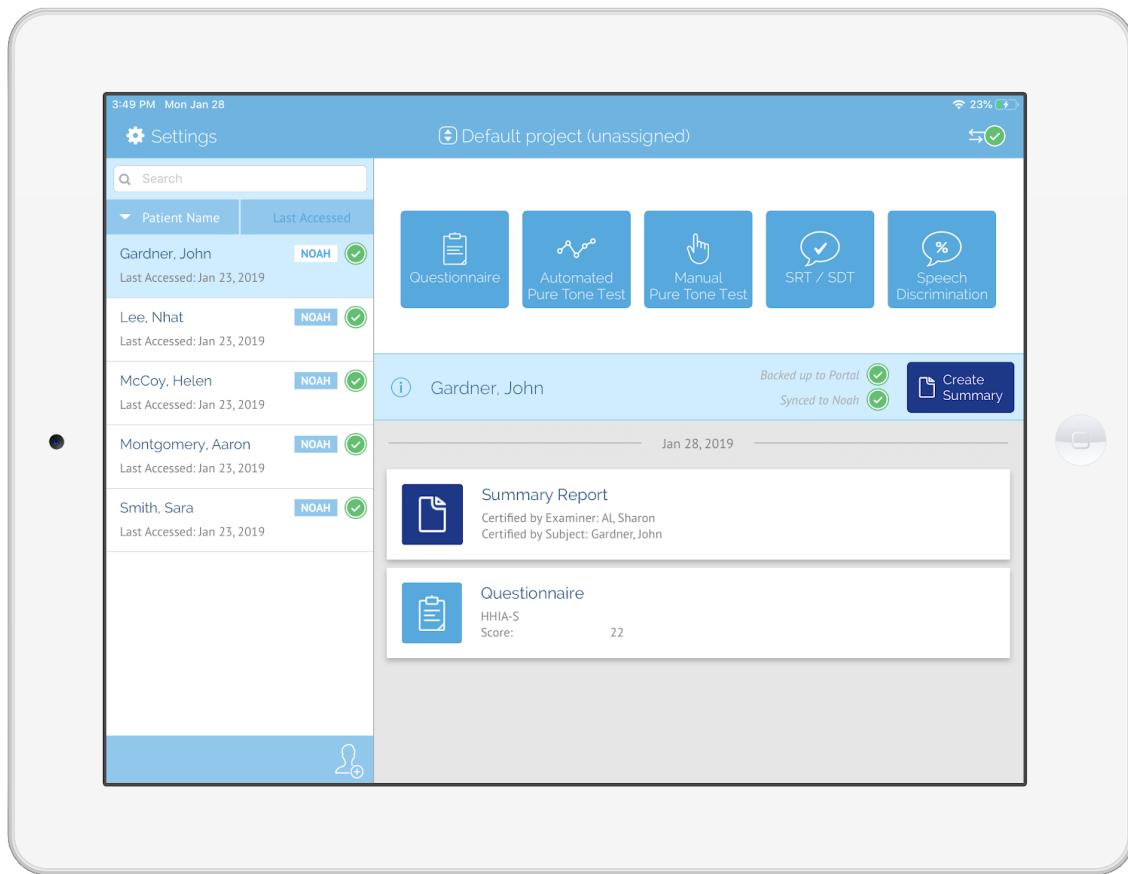




SHOEBOX Audiometry Pro & Noah[®] Integration Guide

Introduction

Welcome to this supplementary guide for customers using SHOEBOS Audiometry Pro. This guide is intended for customers who use Noah in their hearing clinics and want their SHOEBOS audiogram data to be automatically sent to their Noah database.

SHOEBOS Audiometry Pro can be configured to connect to your Noah database, search and retrieve patients, and send the audiogram data from SHOEBOS to your Noah database.

This guide includes four main sections:

- Checking and upgrading your Noah system to the required version.
- Configuring Noah for the SHOEBOS connection.
- Configuring SHOEBOS to connect to Noah.
- Using SHOEBOS, when Noah is enabled.



SHOEBOX Inc.
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Ottawa, ON, Canada K1S 5R5
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1-877-349-9934

SHOEBOX is a Class II medical device listed with
FDA (Registration No: 3007307502)
and Health Canada (License No: 93571).

Intended use: for diagnosis of human hearing loss.

Summary: SHOEBOX Audiometry is an iPad-based
Type 3 Diagnostic Audiometer (as defined in ANSI
S3.6-2010) intended for diagnosis of human
hearing loss.



Notified Body:
BSI Group The Netherlands B.V.



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany



Only applicable to SHOEBOX Audiometry
2797 Software



Applicable to headphone

Australian Sponsor Name:

AA-Med Pty Ltd

Address:

Level 8, 1 Chandos Street,
St Leonards NSW 2065
Australia

SB-QMS-760 Rev: B / 2019-03

Legend:



Catalog Number



Manufacturer



Authorized Representative



Consult IFU

A paper copy of this document is available upon request.

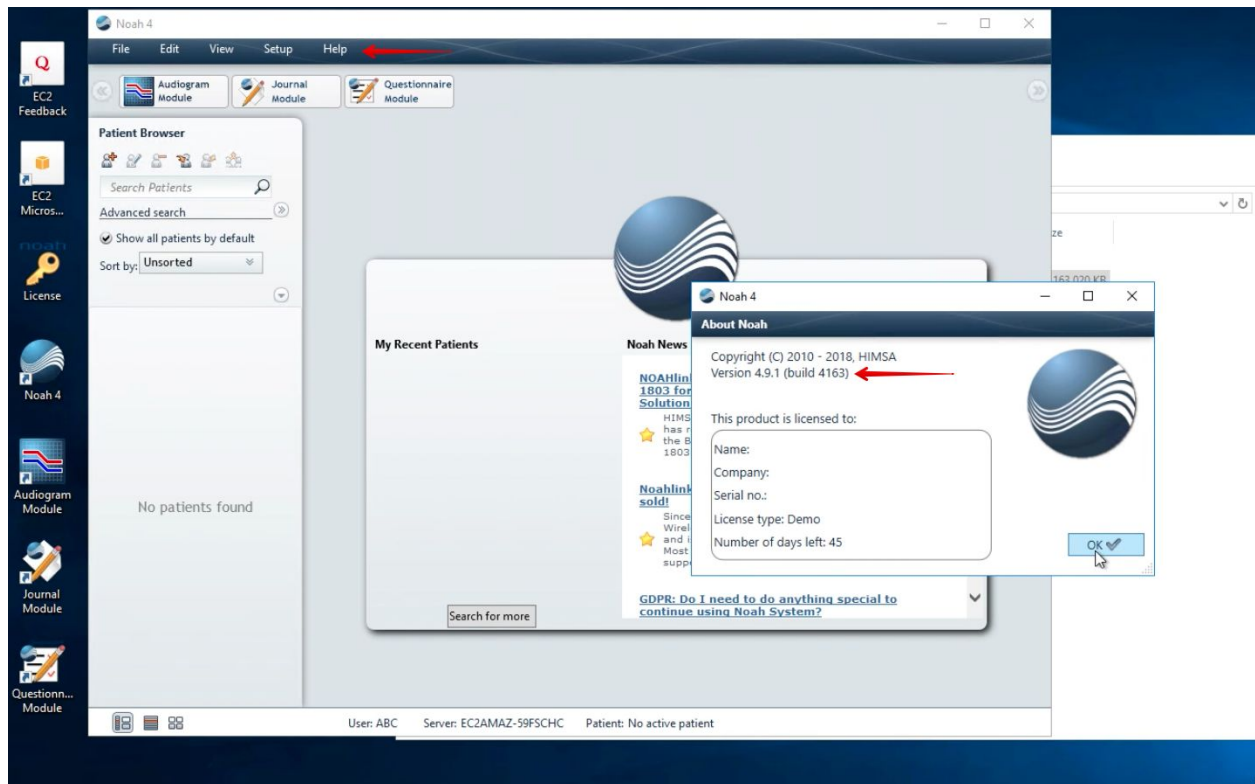
Configuring Noah for SHOEBOX Connection

System Requirements

- Noah version: 4.9.1
- Noah Mobile must be enabled.
- Admin user on Noah must be used. For security reasons, this cannot be the default user provided with the initial Noah installation.
- Note: In order for Office Management Systems (OMS) to synchronize data through Noah to SHOEBOX, the OMS must use the minimum supported Noah version listed above and be compatible with the Noah Mobile feature.

Checking and Upgrading Noah

SHOEBOX can successfully integrate with any Noah version 4.9.1 or later. You can check which version of Noah you have installed by opening Noah, clicking on the 'Help' menu then selecting 'About Noah'. This will display a small dialog window with the Noah version information.

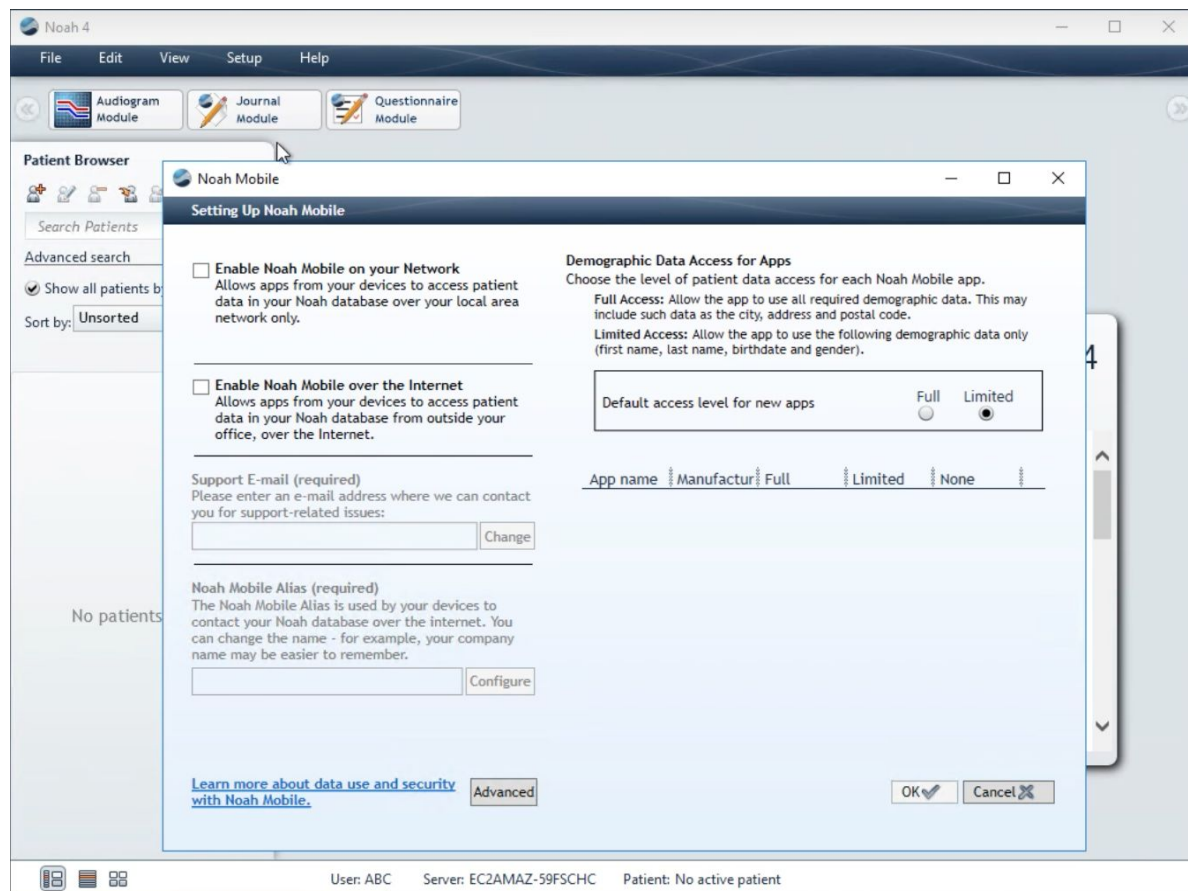


If your Noah installation is on a version prior to 4.9.1, you'll need to first upgrade Noah before completing any additional setup. You can download the Noah upgrade package from the HIMSA website <https://www.himsa.com/en-us/download/noahsystem.aspx>

Noah Mobile Setup

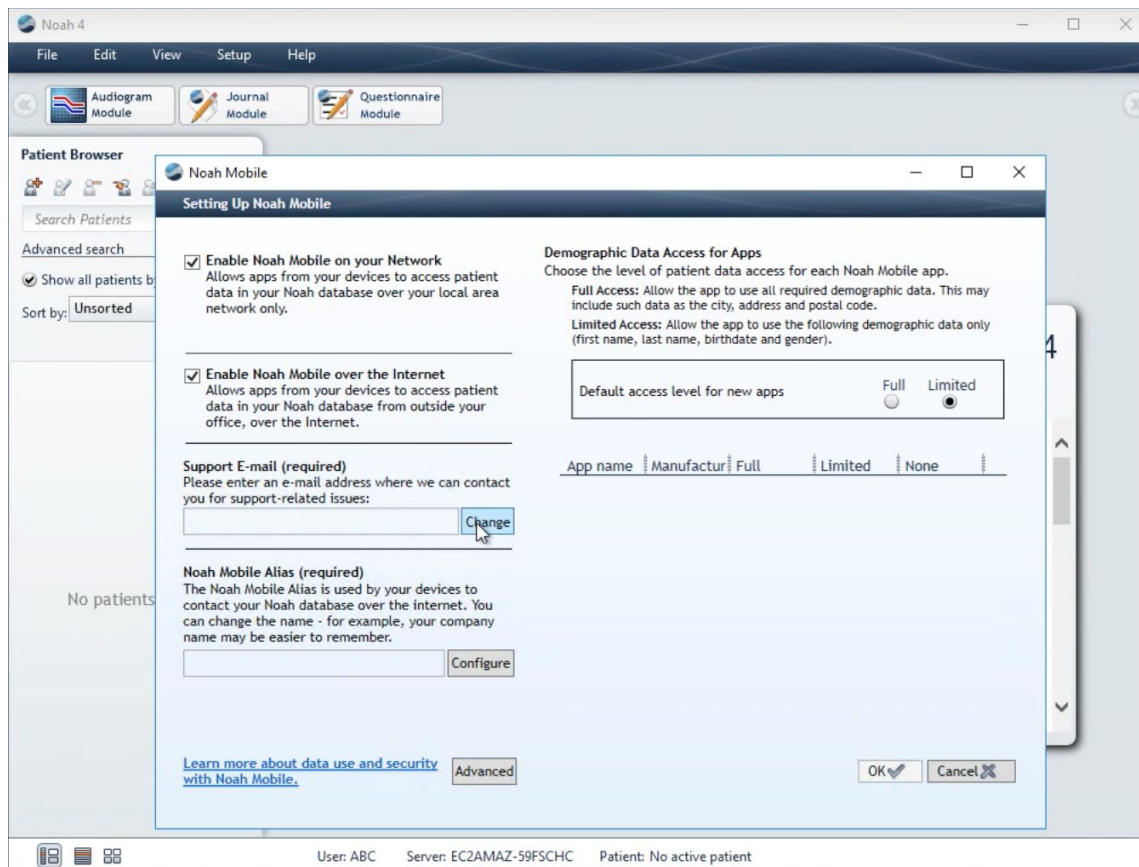
SHOEBOX makes use of the Noah integration feature called [Noah Mobile](#). Unless you're already using modules that use this feature, it is likely that this has not yet been configured for your Noah installation. The following steps will guide you through the Noah Mobile setup process.

Step 1. From within Noah, click the 'Setup' menu item, select 'Administration' and then 'Noah Mobile Configuration'. This will bring up a configuration window.

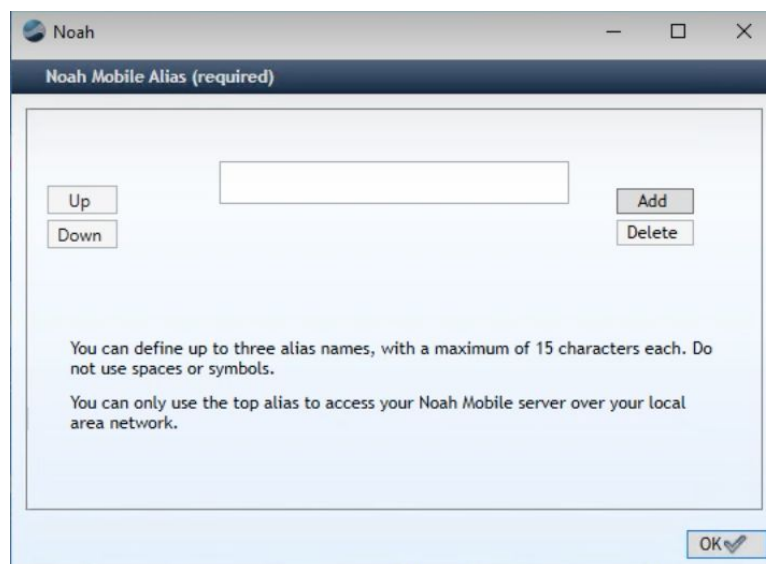


Step 2. Within the configuration window, click to enable both 'Enable Noah Mobile on your Network' and 'Enable Noah Mobile over the Internet'.

Step 3. Completing step 2 will cause the 'Support E-mail' field to become enabled. Click 'Change' to set an email for Noah to use when communicating about support issues.



Step 4. Set your Noah Mobile Alias. This alias is the name you'll use to uniquely identify your Noah database. It's a good idea to make sure this name is something simple that you'll remember. One possible option is to use your clinic name.



Click 'Add' to enter the alias of your choice and the 'OK' to confirm. Noah will then take a few minutes to confirm that the name you've chosen hasn't already been used by another user. If it's OK, you'll be onto the next step, otherwise you may be asked to choose another name.

Step 5. Once you've set and confirmed your Noah Mobile Alias, you can click 'OK' on the Noah Mobile Configuration window to finish the configuration steps.

Step 6. Completing step 5 will cause another window to be displayed requesting that you read and agree to Noah's Data Security Access Agreement. Selecting the country you're doing business in from the dropdown at the top of the window will cause the correct agreement to be displayed.

Business Location: Select a Country

- Azərbaycan (Azərbaycan dili) (Azerbaijan)
- België (Nederlands) (Belgium)
- Belgique (français) (Belgium)
- Belize (English) (Belize)
- Bolivia (español) (Bolivia)
- Qullasuyu (runasimi) (Bolivia)
- Bosna i Hercegovina (bosanski) (Bosnia and Herzegovina)
- Bosna i Hercegovina (hrvatski) (Bosnia and Herzegovina)
- Bosna i Hercegovina (srpski) (Bosnia and Herzegovina)
- Botswana (Setswana) (Botswana)
- Brasil (português) (Brazil)
- Brunei (Bahasa Melayu) (Brunei)
- Cameroun (français) (Cameroon)
- Canada (français) (Canada)
- Kanien'kéha (Canada)
- Canada (English) (Canada)
- caraïbes (français) (Caribbean)
- Caribbean (English) (Caribbean)
- Caribbean (Papiamentu) (Caribbean)
- Česká republika (čeština) (Czech Republic)

Name of Approver:

E-mail:

Job Title:

Company Name:

☐ I have read and accept the terms of this agreement.

Save ✓ Cancel ✕

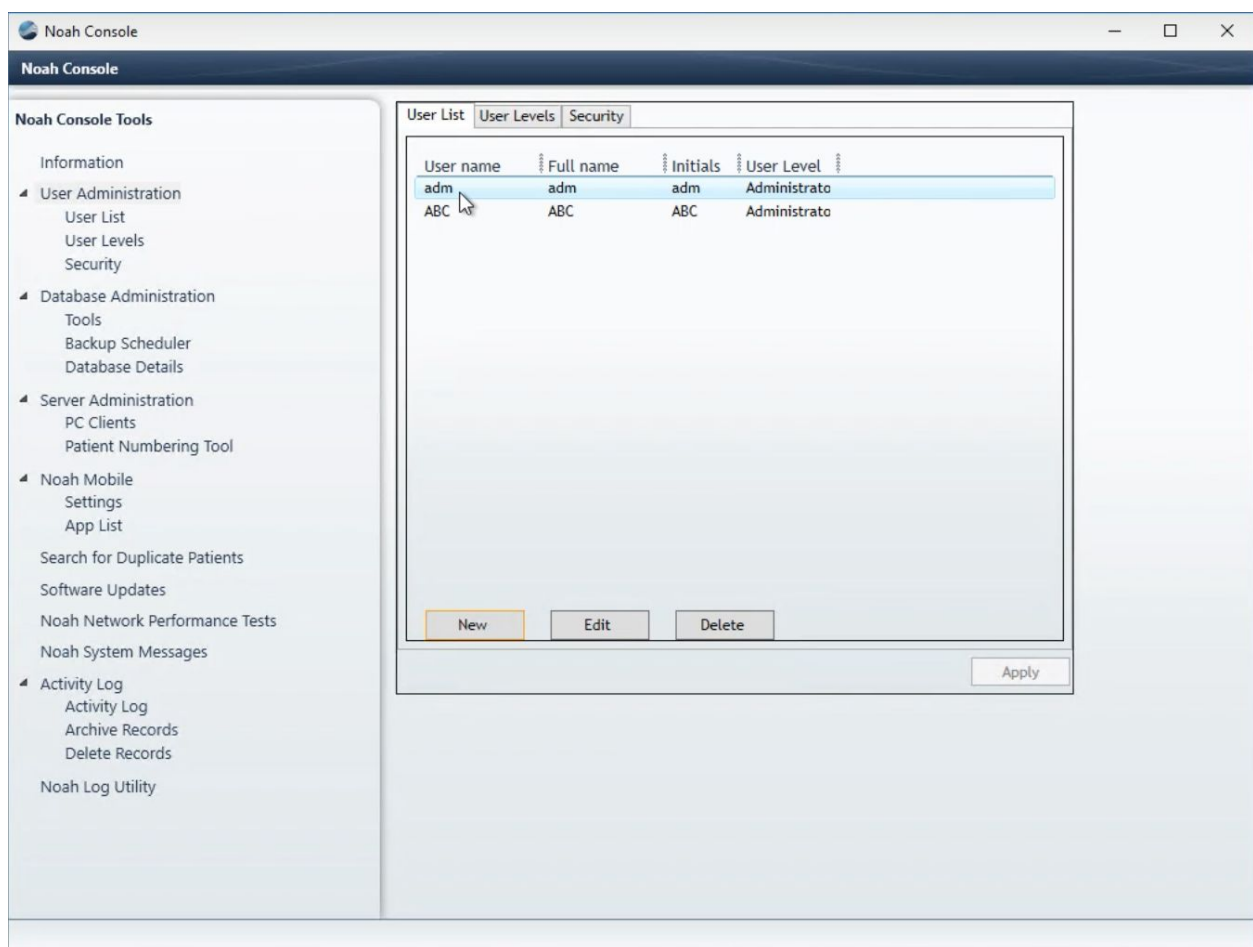
Step 7. Once you've read the agreement, you can then fill out the fields below it, click to accept the agreement and then save. A copy of this agreement will then be emailed to the email entered above.

If you've followed these steps to the end, then your Noah installation is now set up and configured to use Noah Mobile.

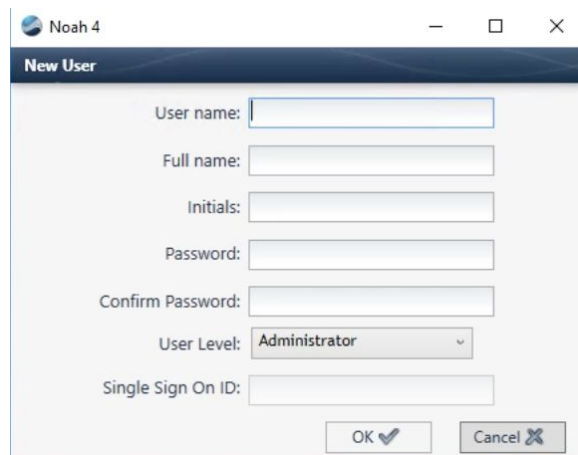
Configuring Users

Noah usually comes with 2 default users ('ABC' and 'adm'), however these users don't provide the level of security that is required for use with Noah Mobile. If you haven't already set up your own administrative user with an enabled password, you'll need to do that now.

From within Noah, click the 'Setup' menu item, select 'Administration' and then 'User Administration'. This will bring up a user administration window listing the currently available users.



To create a new user, click the 'New' button and then proceed to fill in the user details in the window that is displayed. Make sure the 'User Level' is set to Administrator.



The screenshot shows a 'New User' dialog box from the Noah 4 application. The dialog box has a title bar with 'Noah 4' and standard window controls. Below the title bar, the text 'New User' is displayed. The main area contains several input fields: 'User name:', 'Full name:', 'Initials:', 'Password:', 'Confirm Password:', and 'Single Sign On ID:'. There is also a 'User Level' dropdown menu currently set to 'Administrator'. At the bottom right, there are 'OK' and 'Cancel' buttons.

Note: The very first time you connect to Noah from your SHOEBOX device, you'll need to make sure you provide these administrative credentials. If you would like to use lower level user credentials for subsequent connections, you can set up additional users and set their 'User Level' to either 'Level 1' or 'Level 2'.

Tip: If you're not sure what name to give this administrative user, we suggest using 'shoebox'. This will provide you with an easy to remember name while also giving you a clear view from within Noah of which test results were gathered on your SHOEBOX device.

Note: Any questions or issues regarding your Noah software should be directed to HIMSA support, or your local provider who maintains your office management software.

Configuring SHOEBOX to Connect to Noah

SHOEBOX Security

In accordance with the HIMSA Noah Mobile security requirements, SHOEBOX Audiometry has implemented the following security measures:

- In order to safely regulate user access to device data, SHOEBOX requires that both the SHOEBOX screensaver and passcode be enabled before allowing connection with a Noah server.
- To protect potentially unmonitored data, SHOEBOX monitors for inactivity. After a maximum of 15 minutes of inactivity, the SHOEBOX screensaver will display, covering the screen to hide potential personal data.
- Additionally, as per HIMSA guidelines, after 20 minutes of inactivity, SHOEBOX will automatically log the user off of Noah.
- The first connection established from SHOEBOX to Noah must be established with valid admin credentials for the specified Noah alias. The Noah default users cannot be used for any Noah connections through the Noah Mobile API.

NOTE: The use of patient demographic data obtained from the Noah database is used for the sole purpose of retrieving the required data in the SHOEBOX app for creation and linking of the audiometric data to the patient being tested. The patient demographic data pulled from Noah, and the audiometric data generated by SHOEBOX shall be stored in the secure SHOEBOX data management portal as per the SHOEBOX terms of service, available at <https://www.shoebox.md/ios-terms-of-service/>.

Using SHOEBOX with Noah

SHOEBOX Noah integration is designed to enhance workflows where a patient is initially created in either your OMS or Noah system before testing occurs. This workflow looks something like the following:

In your OMS or Noah:

1. Create your patient

In the SHOEBOX app:

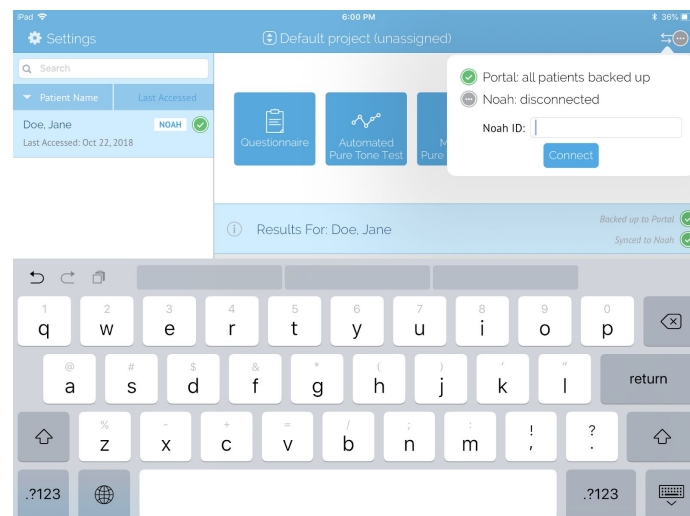
2. Connect to your Noah instance
3. Search for and select Noah patient
4. Complete testing activities
5. Audiogram data is automatically pushed to Noah

Connecting to Noah

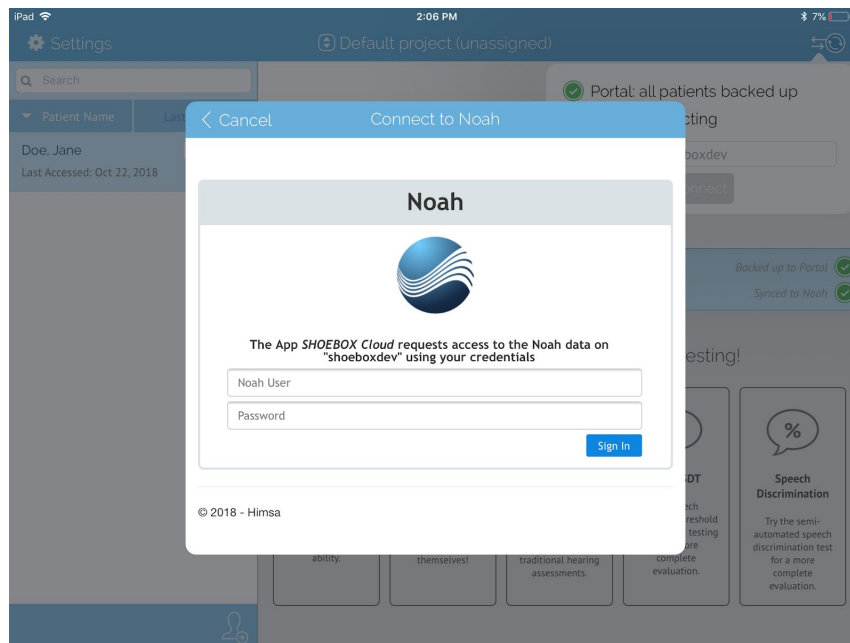
1. From the SHOEBOX home screen, locate the connection status icon in the top right corner and tap to bring up the connection dialog.



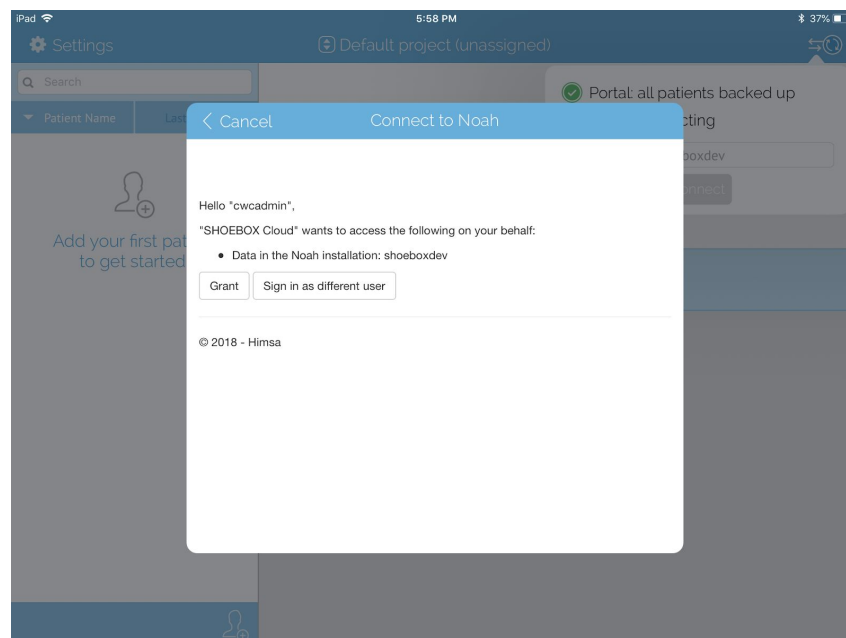
2. You'll be prompted to enter your Noah ID (this is the Noah alias that was set up in step 4 of 'Noah Mobile Setup').



3. You will be presented with a “Connect to Noah” window where you will enter the Noah User and Password that you configured in the previous section, and then select “Sign In”.

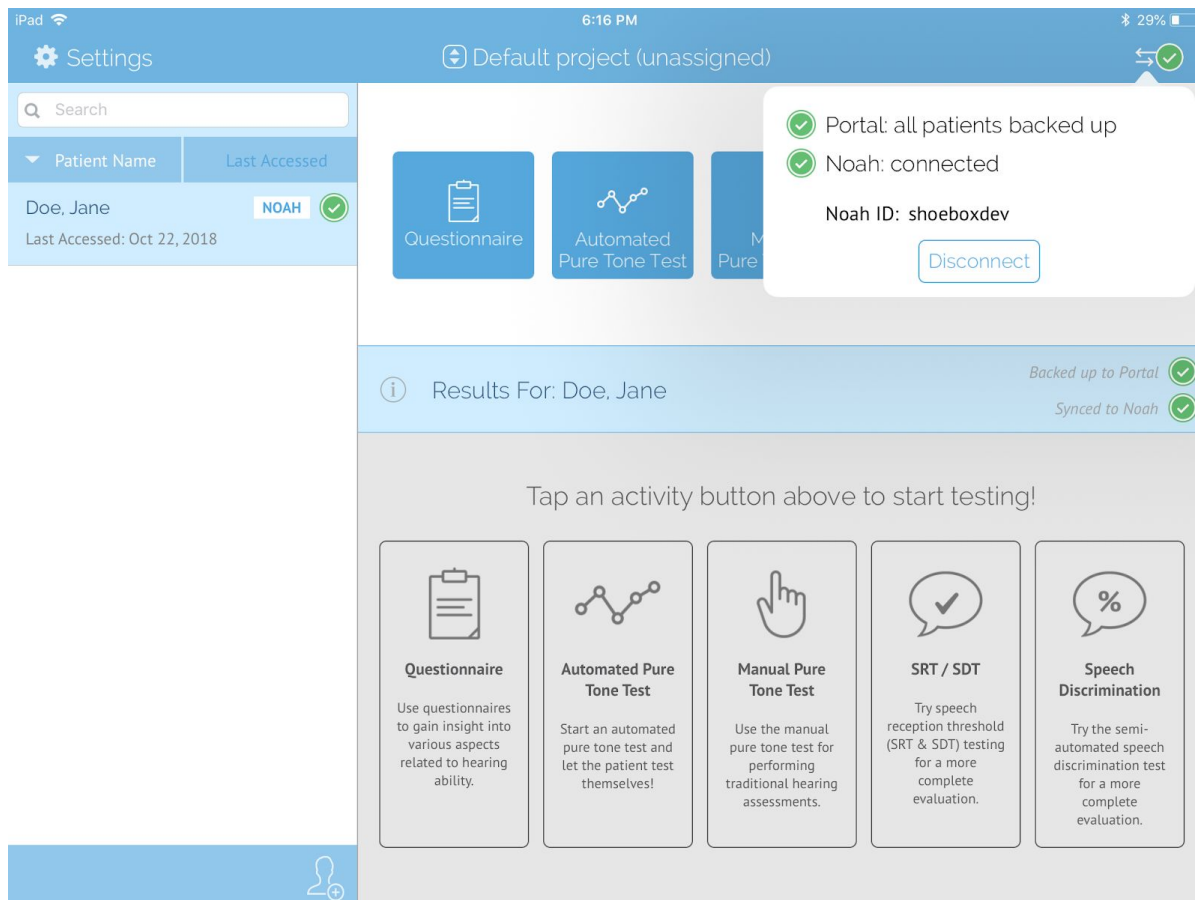


4. You will then be presented with a second window where you can select “Grant” to confirm the connection. From this screen you can also log in with different user credentials by selecting “Sign in as different user”.



Please note that the first time you complete this connection step you will need to provide administrative Noah user credentials. After the initial set-up, type 1 or 2 user credentials can be provided.

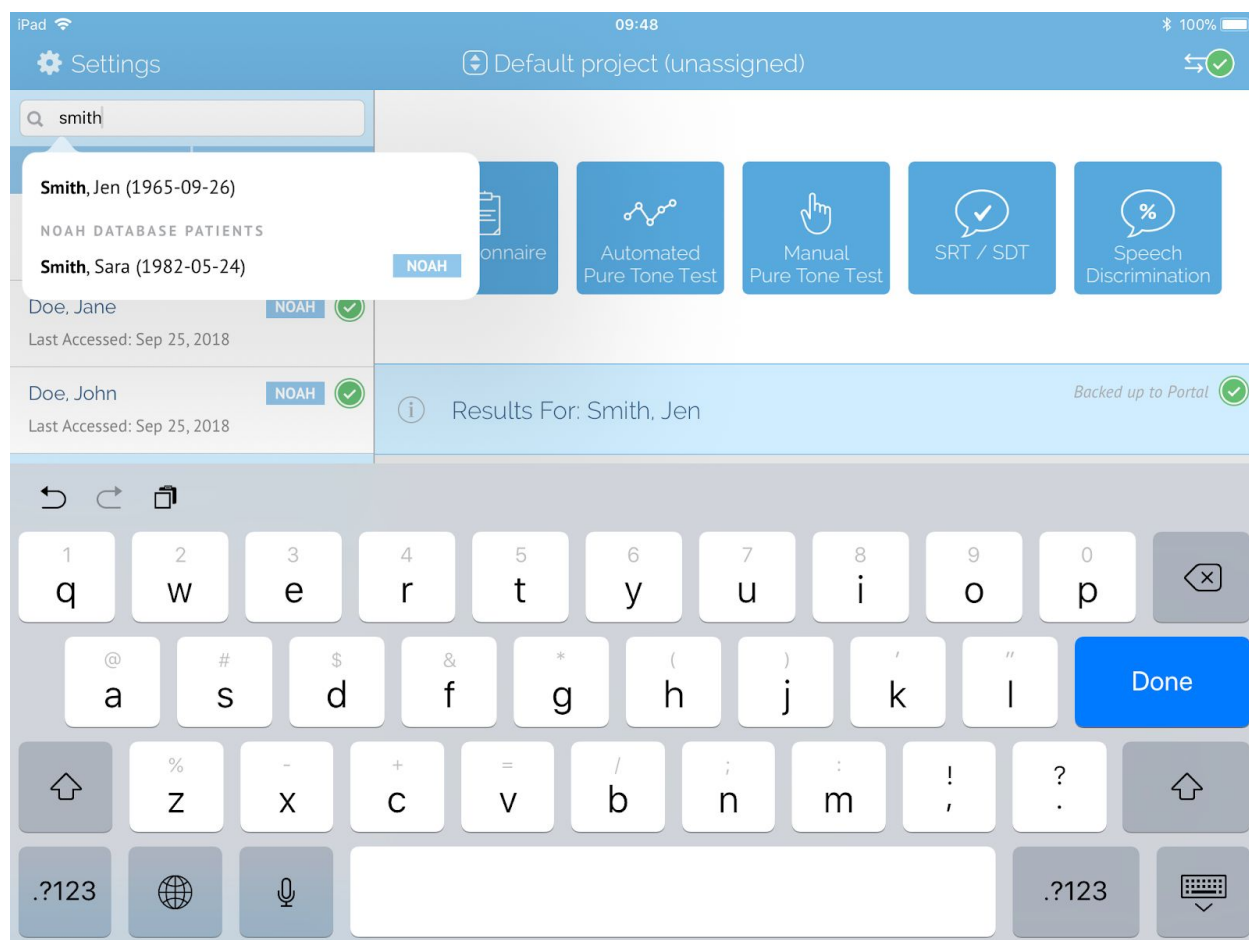
Once the connection is successfully established, the connection status icon will display a green check symbol and tapping it will display the status dialog with a message indicating this.



Searching for a Noah Patient

Once you've connected to your Noah instance, you can search for patients in your Noah database by tapping on the search bar at the top of the SHOEBOX home screen and typing the patient's name.

Once you've started typing, SHOEBOX will start trying to find patients matching the search criteria. Patients that have been created with SHOEBOX or have already been retrieved from Noah will be listed first, followed by those new matches found in the Noah database.



Patients that have been previously pulled from your Noah database or are currently only residing in your Noah database will be marked with a 'NOAH' tag

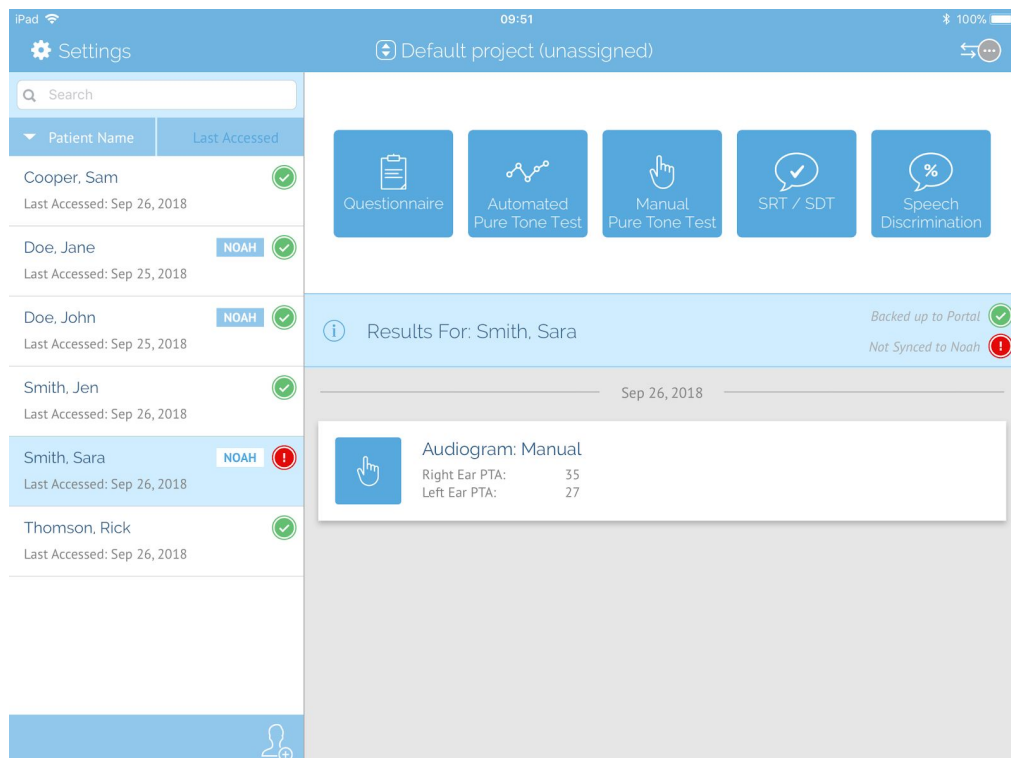
Run the audiogram test

No special action is required to complete Noah compatible audiogram results. With a Noah patient selected, simply tap to complete a manual or automated hearing test as you normally would (Refer to the SHOEBOX Pro User Guide for more information on completing those tests).

Push the audiogram results to Noah

Once the test has been completed, return back to the SHOEBOX home screen. SHOEBOX will automatically push the new test result to the Noah system you are connected to. You can verify it has been successfully pushed by checking the patient connection status in the patient list.

- A green  icon indicates that everything has been pushed successfully.
- A red  icon indicates that the patient has audiogram data that hasn't yet been pushed to Noah.



You can also confirm the status of the audiogram result being pushed to Noah by reviewing the status information for a selected patient. This method may provide more information when troubleshooting issues.

Troubleshooting

Error Messages

Message	Meaning	Action Required
Error: mandatory field	A mandatory field has not been filled in.	User must provide the Noah alias as well as a username and password of a valid Noah user in order to connect.
Error: admin user required for first login	The SHOEBOX app has not yet been registered with your Noah system and an administrative user is required for the initial login.	User must provide username and password for a Noah administrative user.
Error: external service version is not supported	Noah is on an unsupported version.	Noah needs to be upgraded to version 4.9.1 or higher. See 'Checking and Upgrading Noah'
Error: invalid external service alias	The Noah alias ID was incorrect.	Double check that the entered Noah alias ID is typed correctly and matches the alias you set in the initial set-up process.
Error: invalid username or password	The username or password was incorrect.	Double check that the username and password provided match credentials for a valid Noah user. In rare cases this message would also be displayed if your Noah server is not connected to the internet.

Status Indicators

Icon	Meaning	Possible Cause
	SHOEBOX is syncing patient data with the SHOEBOX Data Management web portal or Noah.	Update made to patient.
	SHOEBOX was unable to push audiogram results from this patient to either Noah or the SHOEBOX Portal.	No internet connection. Not connected to Noah. In very rare cases this may be caused by unexpected data transfer. If re-establishing connection to Noah does not resolve this issue, please contact SHOEBOX support.
	SHOEBOX is not experiencing any issues. All data has been pushed to expected locations.	
	All audiogram data has been pushed to Noah but SHOEBOX is not currently connected to Noah.	No internet connection. Not connected to Noah.

Note: if you have disabled backups to the SHOEBOX Data Management web portal (not recommended), then the status indicator beside the patient will remain in the red error state.